

Notice of Allowability

Application No.

09/671,461

Applicant(s)

STABY, ARNE

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/11/06.
2. ☒ The allowed claim(s) is/are 2,4,6,11-25 and 27-29.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/522,694.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 20051230.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application
- ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
- ☒ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

DETAILED ACTION

Status of the Claims

1. Claims 2, 4, 6, 11-25 and 27-29 are pending.

Applicants' amendment filed on July 11, 2006 is acknowledged. Applicants' response has been fully considered. Claims 2, 4, 21 and 27 have been amended, and claim 26 has been cancelled. Thus, claims 2, 4, 6, 11-25 and 27-29 are examined.

Withdrawn Informalities

2. The previous objection to the specification, regarding the term "Arg³⁴GLP-1₍₇₋₃₇₎", is withdrawn in view of applicants' submission of a substitute specification, and applicants' response at page 8 of the amendment filed July 11, 2006.

Withdrawn Claim Objection

3. The previous objection to claims 15 and 23, regarding the term "Arg³⁴GLP-1₍₇₋₃₇₎", is withdrawn in view of Examiner's Amendment (see below).

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 2, 4, 6 and 11-29, under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' amendment of the claim, applicants' cancellation of the claim, and applicants' response at pages 8-9 in the amendment filed July 13, 2006.
5. The previous rejection of claims 2, 4, 6 and 11-25, under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment of the claim, and applicants' response at page 9 in the amendment filed July 13, 2006.

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Objection to Drawings

4. The drawings remain objected to, please see the notice of draftsperson's drawing review mailed January 11, 2006.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard W. Bork on September 28, 2006.

Examiner's Amendments to the specification:

Please replace the paragraph at page 1, lines 4-8 of the substitute specification filed July 11, 2006 with the following paragraph:

This application is a divisional of 09/522,694 filed March 10, 2000, now U. S. Patent 6,451,987 and claims priority under 35 U.S.C. 119 of U.S. provisional application nos. 60/125,882 and 60/179,335 filed March 24, 1999 and January 31, 2000, respectively, and of Danish application nos. 1999 00360 and 2000 00083 filed March 15, 1999 and January 19, 2000, respectively, the contents of which are fully incorporated herein by reference.

Please replace the subtitle "Description of the Invention" at page 2, line 4 of the substitute specification filed July 11, 2006 with the subtitle "BRIEF SUMMARY OF THE INVENTION".

Please insert the following paragraphs after the paragraph that ends at page 6, line 13 of the substitute specification filed July 11, 2006:

BRIEF DESCRIPTION OF THE DRAWINGS

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FIG. 1 is a chromatograph obtained as described in Example 1.

FIGS. 2-3 are chromatographs of the sample for application and the eluate obtained as described in Example 1.

FIG. 4 is a chromatograph obtained as described in Example 3.

FIG. 5 is a chromatograph obtained as described in Example 5.

FIG. 6 is a chromatograph obtained as described in Example 9.

FIG. 7 is a chromatograph obtained as described in Example 10.

FIG. 8 is a chromatograph obtained as described in Example 11.

FIG. 9 is a chromatograph obtained as described in Example 12.

FIG. 10 is a chromatograph obtained as described in Example 13.

FIG. 11 is a chromatograph obtained as described in Example 14.

FIG. 12 is a chromatograph obtained as described in Example 16.

Examiner's Amendment to the Claims:

Claims 15 and 23 have been amended as follows:

15. (Currently amended) The method according to claim 2, wherein the peptide is selected from the group consisting of Val⁸GLP-1(7-37), Thr⁸GLP-1(7-37), Met⁸GLP-1(7-37), Gly⁸GLP-1(7-37), Val⁸GLP-1(7-36) amide, Thr⁸GLP-1(7-36) amide, Met⁸GLP-1(7-36) amide, Gly⁸GLP-1(7-36) amide, ~~Arg³⁴GLP-1(7-37)~~ Arg³⁴GLP-1(7-37), and B28IsoAsp insulin.

23. (Currently amended) The method according to claim 22, wherein said glucagon-like peptide-1 analog is selected from the group consisting of Val⁸GLP-1(7-37), Thr⁸GLP-1(7-37), Met⁸GLP-1(7-37), Gly⁸GLP-1(7-37), Val⁸GLP-1(7-36) amide, Thr⁸GLP-1(7-36) amide, Met⁸GLP-1(7-36) amide, Gly⁸GLP-1(7-36) amide and ~~Arg³⁴GLP-1(7-37)~~ Arg³⁴GLP-1(7-37).

The following is an Examiner's Statement of Reasons for Allowance: The following reference appears to be the closest art to the claimed invention. Korc *et al.* (US 2003/0103980, priority date October 16, 1998) teach GAG-containing forms of glypican-1 and syndecan-1 were purified by anion exchange chromatograph on DEAE-Sephacel equilibrated in buffer A (50 mM

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Tris-HCl, pH 8.0, 0.15 M NaCl, 0.1% triton X-100). Cell lysates containing glypican-1 or syndecan-1 in buffer B (50 mM Tris-HCl, pH 8.0, 0.15 M NaCl, 0.1% triton X-100, 1mM EDTA, 1 µg/ml pepstatin A, 1 mM PMSF) were loaded onto columns, and columns were eluted stepwise with buffer A, buffer C (50 mM Tris-HCl, pH 8.0, 0.25 M NaCl, 0.1% triton X-100), buffer D (50 mM Tris-HCl, pH 8.0, 6 M urea, 0.25 M NaCl, 0.1% triton X-100), and buffer E (50 mM sodium formate, pH 3.5, 0.2 M NaCl, 6 M urea, 0.1% triton X-100). After restoring the pH with 50 mM Tris-HCl, pH 8.0, 0.1% triton X-100, glypican-1 or syndecan-1 was eluted from the column with buffer F (50 mM Tris-HCl, pH 8.0, 0.75 M NaCl, 0.1% triton X-100). However, the reference does not teach a method for purifying a peptide from a mixture comprising the peptide and related impurities, the method comprising: a) eluting the related impurities of the mixture from an anion exchange chromatography matrix using a solution comprising an organic modifier, water, and a buffer, and optionally a salt component; and without an intervening step, b) subsequently, eluting the peptide with an aqueous solution in the absence of an organic modifier, at the same or lower pH-value. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

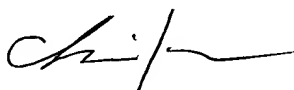
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



Primary

**CHIH-MIN KAM
PATENT EXAMINER**

CMK

September 28, 2006